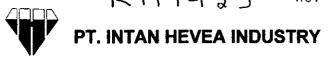
K111923 NOV - 4 201



Jalan Pulau Irian No. 13 Kawasan Industri Medan I Jalan Yos Sudarso Km 10.5. Medan 20371. INDONESIA.

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Email intanhevea@yahoo.com

510k Summary

1.0 Submitter:

Name : PT. INTAN HEVEA INDUSTRY

Address : Jalan Pulau Irian No.13

Kawasan Industri Medan I Jalan Yos Sudarso Km 10.5 Medan 20371, INDONESIA

Phone No. : +62-61-6850169, 6856335 Fax No. : +62-61-6850168, 6856335

Date of Summary Prepared : September 19, 2011

2.0 Contact Person:

Name : Darwin Tandjo

Phone No. : +62-61-6850169, 6856335 Fax No. : +62-61-6850168, 6856335

3.0 Name of the Device:

Trade Name : SKIN GUARD and Multiple or Customer's Trade Name

Device Name : Powder Free Latex Examination Gloves, Non Sterile

(contains 50 micrograms/ dm² or less of total water

extractable protein).

Common Name : Examination Gloves

Classification Name : Patient Examination Gloves (Class I)

4.0 Identification of The Legally Marketed Device (Predicate Device) which Substantially Equivalent:

The Powder Free Latex Examination Gloves, Non Sterile (contains 50 micrograms/dm² or less of total water extractable protein) are substantially equivalent with Latex Patient Examination Gloves, Powdered, Non-Sterile submitted and cleared under 510(k) number K894480. The different in this submission is the product Powder Free, Non Sterile with labeling claim contains 50 micrograms/dm² or less of total water extractable protein with no change in product design.

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5.0 Description and Specification of The Device:

The Powder Free Latex Examination Gloves, Non Sterile (contains 50 micrograms/dm² or less of total water extractable protein) is Class I Device. These gloves are made of natural rubber latex. The gloves can be used either right or left hand (ambidextrous), Disposable, Single Use and Non Sterile. The Specification of this device meets the requirements of ASTM Standard D 3578 – 05 and FDA 1000ml Water Leak Test.

6.0 Intended Use of the Device:

The Powder Free Latex Examination Gloves (contains 50 micrograms/dm² or less of total water extractable protein) is a disposable device intended for medical purpose that is worn on the examiners hand and finger to prevent contamination between patient and examiner.

7.0 Summary of The Technological Characteristics of The Device:

The Powder Free Latex Examination Gloves, (contains 50 micrograms/dm² or less of total water extractable protein) technological characteristics are summarized in the following information compared with ASTM or equivalent standards;

| Characteristics | Standards | Performance |
|-----------------------|----------------------------|-------------------------|
| Dimensions | D 3578 - 05 | Meets |
| Physical Properties | D 3578 – 05 | Meets |
| Freedom from Pinholes | FDA 21 CFR 800.20 | Meets |
| Powder Residue | D 3578 – 05 | <2 mg/gloves |
| | D 6124 - 06 | _ |
| Water Soluble Protein | D 3578 – 05 | < 50μg/dm ² |
| Content | D 5712 – 10 | , 3 |
| Biocompatibility | 16 CFR Ch.II 1500, 4.1 | Passes (No primary skin |
| | Primary Skin Irritation in | irritation) |
| | Rabbits | |
| _ | ASTM F720-81 Dermal | Passes (No contact |
| | Sensitization | sensitizer) |

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data:

The performance test data of the non clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

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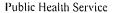
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9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:
Clinical data is not needed for gloves or for most devices cleared by the 510k process.

10.0 Conclusion:

It can be concluded that the data of Powder Free Latex Examination Gloves, Non Sterile (contains 50 micrograms/dm² or less of total water extractable protein) meets ASTM Standards and FDA requirements for water leak test. No skin irritation and skin sensitization detected during the animal study. The data demonstrates Substantially Equivalent and perform as safe, as effective as well as currently marketed devices or predicated device.







Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

NOV - 4 2011

Mr. Darwin Tandjo Factory Manager PT. INTAN HEVEA INDUSTRY Jalan Pulau Irian No.13 Kawasan Industri Medan I Jalan Yos Sudarso Km 10.5. Medan 20371 INDONESIA

Re: K111923

Trade/Device Name: POWDER FREE LATEX EXAMINATION GLOVES, NON

STERILE

(contains 50 micrograms/dm2 or less of total water extractable

protein per gram).

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I Product Code: LYY Dated: October 7, 2011 Received: October 11, 2011

Dear Mr. Tandjo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Page 2 – Mr. Tandjo

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/Lucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital, Infection Control and Dental Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure



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INDICATIONS FOR USE.

| Applicant | : PT. Intan Hevea Industry. | |
|---|--|--|
| 510(k) Number (if known) | : <u>K111923</u> | |
| Device Name | : POWDER FREE LATEX EXAMINATION GLOVES, NON STERILI (contains 50 micrograms/dm² or less of total water extractable protein per gram). | |
| Indications for Use : | | |
| total water extractable prot | tion Gloves, Non Sterile (contains 50 micrograms/dm ² or less of tein) is a disposable device and made of Natural Rubber Latex uses that is worn on the examiner's hand or finger to prevent tient and examiner. | |
| Prescription Use Per 21 CFR 801 Subpart D) | AND/ ÓR Över-The-Counter Use V (Per 21 CFR 801 Subpart C) | |
| PLEASE DO NOT WRITE BELO | OW THIS LINE - CONTINUE ON OTHER PAGE IF NEEDED) | |
| Concurrence of CDRH, Office | e of Device Evaluation (ODE) | |

Equation Sign-Off)

Division of Anesthesiology, General Hospital

Infection Control, Dental Devices

510(k) Number: <u>KIII 923</u>